



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1800-NC2]

Inflation Reduction Act (IRA) Initial Program Guidance; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' initial guidance for the Medicare Drug Price Negotiation Program for the implementation of the Inflation Reduction Act. CMS will be releasing additional Inflation Reduction Act-related guidance; all can be viewed on the dedicated Inflation Reduction Act section of the CMS web site at <https://www.cms.gov/inflation-reduction-act-and-medicare/>.

DATES: Comments must be received by April 14, 2023.

ADDRESSES: Written comments should be sent to IRARebateandNegotiation@cms.hhs.gov with the relevant subject line, "Medicare Drug Price Negotiation Program Guidance."

SUPPLEMENTARY INFORMATION: The Inflation Reduction Act was signed into law on August 16, 2022. Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (Pub. L. 117-169) established the Medicare Drug Price Negotiation Program (hereafter the "Negotiation Program") to negotiate Maximum Fair Prices (MFPs) for certain high expenditure, single source drugs and biological products. The requirements for this program are described in sections 1191 through 1198 of the Social Security Act (hereafter "the Act") as added by sections 11001 and 11002 of the Inflation Reduction Act.

To obtain copies of the Negotiation Program initial guidance and other Inflation Reduction Act-related documents, please access the CMS Inflation Reduction Act web site by copying and pasting the following web address into your web browser:

<https://www.cms.gov/inflation-reduction-act-and-medicare>. If interested in receiving CMS Inflation Reduction Act updates by email, individuals may sign up for CMS Inflation Reduction Act's email updates at <https://www.cms.gov/About-CMS/Agency-Information/Aboutwebsite/EmailUpdates>.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: March 13, 2023.

Evell J. Barco Holland,
Federal Register Liaison,
Centers for Medicare & Medicaid Services.

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